REMARKS

Formal Matters

Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-301 are pending after entry of the amendments set forth herein.

Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-300 were examined. Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-300 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

Request for Withdrawal of the Finality of the Office Action as being Premature

The Office Action

Objections to Drawings

In the Official Action of July 25, 2007, the drawings were objected to. The Examiner referred to 37 CFR 1..83(a) and asserted that the drawings must show every feature of the invention specified in the claims. Accordingly, The Examiner asserted that "inserting said ablative device through the at least one lumen having a radially asymmetric geometry", "temperature sensor" and "assessing the electrical isolation..." must be shown of the features canceled from the claims.

In response thereto, Applicants note that 37CFR 1.81(a) states, in part:

(a) The applicant for a patent is required to furnish a drawing of his or her invention where necessary for the understanding of the subject matter sought to be patented.

Given that the Examiner has repeatedly taken "Official Notice" that sensing temperature in ablation systems is "notorious" (e.g., see sentence bridging pages 9-10 of the Office Action dated July 25, 2007), it appears difficult to logically square this assertion with the Examiner's implication that a drawing of a temperature sensor is needed in order for the Examiner to understand the invention.

Nevertheless, in an effort to advance the prosecution of the instant application, Applicants have amended Fig. 11, and is submitting the same herewith in the form of a replacement sheet of drawings, to schematically show a temperature sensor 27t. The specification has also been amended above, at the last paragraph on page 45 to include the reference numeral 27t.

Because 37 CFR 1.83(a) states that conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box), and because the Examiner has repeatedly asserted that temperature sensors are "notorious in the art", temperature sensor 27t has been represented as a labeled rectangular box. Further it is respectfully submitted that this does not constitute the submission of prohibited new subject matter, as temperature sensors were previously described in the specification and because the Examiner has asserted that temperature sensors are "notorious in the art".

With regard to "assessing the electrical isolation", the Examiner has also taken "Official Notice" that it is "notorious in the art" to apply energy to assure that the ablation has been effective, see the first paragraph of page 10 of the Office Action dated July 25, 2007). It therefore appears difficult to logically square this assertion with the Examiner's implication that a drawing of "assessing the electrical isolation" is needed in order for the Examiner to understand the invention. Nevertheless, in an effort to advance the prosecution of the instant application, Applicants have submitted new Fig. 23 herewith as a flowchart showing the steps of the assessment that are carried out as described at last paragraph on page 47 of the specification for example. Additionally, that paragraph has been amended above to refer to the event reference numerals of Fig. 23.

Because "assessing the electrical isolation" is a process, Applicants have submitted a flowchart style drawing illustrating the events carried out for assessing the electrical isolation. Further it is respectfully submitted that this does not constitute the submission of prohibited new subject matter, as the illustrated events were previously described in the specification and because the Examiner has asserted that applying energy to assure that ablation has been effective is "notorious in the art".

With regard to inserting the ablative device through the at least one lumen having a radially asymmetric geometry, the Examiner is referred to Figs. 8 and 9 which show the ablative device having been inserted through a lumen having a radially asymmetric geometry.

Figs. 21 and 22 were objected to as having improper shading. In response thereto, Applicants are submitting a replacement sheet for Figs. 21 and 22 that does not include improper shading.

In view of the above amendments and remarks and submission of replacement and new sheets of drawings, the Examiner is respectfully requested to reconsider and withdraw the objections to the drawings as being no longer appropriate.

Objections to Amendment under 35 U.S.C. Section 132(a)

On page 6, last paragraph of the Office Action dated July 25, 2007, the Examiner objected to the "amendment filed February 7, 2005" as introducing new matter into the disclosure. In response thereto, Applicants respectfully submit that no amendment was either filed or entered in the present application on February 7, 2005.

As to the amendment filed May 2, 2007 in the instant application, Applicants on page 22 of that amendment, traversed the Examiner's assertion that the phrase "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position" constitutes prohibited new matter. However, in order to advance the prosecution of this case, Applicants canceled the objected to claim language, without acquiescing to the Examiner's assertion (see page 15, claim 107 and page 23, first paragraph of the Official Action filed May 2, 2007). Unfortunately, this action does not appear to have advanced the prosecution of the instant application, as the Examiner has merely (and improperly) simply repeated this ground of objection, without addressing Applicants' remarks and amendment in the Amendment filed on May 2, 2007.

M.P.E.P. 707.07(f) requires that:

> In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.
>
> Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.
>
> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

In this case, the Examiner has ignored the amendment of claim 107 and the remarks regarding the same presented in the previous amendment, and has repeated an objection regarding new matter, without addressing Applicants' amendment or remarks. As such, it is respectfully submitted that the Office Action dated July 25, 2007 is incomplete and not fully responsive to Applicants amendments and remarks. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed

concurrently herewith, the Examiner is respectfully requested to address the amendment and remarks made by Applicants in the previous amendment which Applicants have referred to above.

It is respectfully submitted that this ground of objection is clearly inappropriate and should be withdrawn.

Rejection of Claim 107 under 35 U.S.C. Section 112, First Paragraph

Claim 107 was rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. The Examiner asserted that claim 107 contains subject matter which was not described in the specification in such a way to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed , had possession of the claimed invention, as the Examiner asserted that the originally filed disclosure is silent on "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position".

Applicants respectfully traverse this ground of rejection as being clearly erroneous. It is respectfully submitted that claim 107 does not recite "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position",

In the amendment filed May 2, 2007 in the instant application, Applicants on page 22 of that amendment, traversed the Examiner's assertion that the phrase "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position" constitutes prohibited new matter. However, in order to advance the prosecution of this case, Applicants canceled the objected to claim language, without acquiescing to the Examiner's assertion (see page 15, claim 107 and page 23, first paragraph of the Official Action filed May 2, 2007). Unfortunately, this action does not appear to have advanced the prosecution of the instant application, as the Examiner has merely (and improperly) simply repeated this ground of rejection of claim 107, without addressing Applicants' remarks and amendment in the Amendment filed on May 2, 2007.

M.P.E.P. 707.07(f) requires that:

> In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.
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> Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.
>
> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

In this case, the Examiner has ignored the amendment of claim 107 and the remarks regarding the same presented in the previous amendment, and has repeated the rejection of claim 107 under 35 U.S.C. Section 112, first paragraph, while rejecting language that does not appear in claim 107 as presenting prohibited new matter. Furthermore, the Examiner has ignored the amendment of claim 107 and remarks made in that regard. As such, it is respectfully submitted that the Office Action dated July 25, 2007 is incomplete and not fully responsive to Applicants amendments and remarks. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed concurrently herewith, the Examiner is respectfully requested to address the amendment and remarks made by Applicants in the previous amendment which Applicants have referred to above.

It is respectfully submitted that this ground of rejection is clearly inappropriate and should be withdrawn.

Claim Rejected Under 35 U.S.C. Section 102(b) (Roth et al.)

Claim 106 was rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al.

Because the Examiner did not identify the patent number of Roth et al. with specificity, Applicants have assumed that the Examiner has referred to Roth et al., U.S. Patent No. 5,207,672. Applicants note that this ground of rejection was previously applied by the Examiner in the Official Action dated March 26, 2006. In the Amendment filed July 12, 2006 in response to the Office Action of March 12, 2006, Applicants amended claim 106 and traversed this ground of rejection, asserting:

> "Thus, Roth et al.'s object is to damage the tissue by coagulation necrosis, so that the tissue dies and is later sloughed off during urination. This is not the same process as ablation, as is the subject of the present invention. Ablation according to the present invention causes a lesion of scar tissue which is not sloughed off, but remains to function as an electrical conduction block. See also, the background section of the present application at page 3, lines 20-24 that indicate that a potential disadvantage of RF ablation catheters is the risk of clot formation, which can cause potentially lethal strokes. Coagulation necrosis cause clots, and the sloughing off of such tissue would pose a significant risk to the procedures described in the present application.
>
> Further, Roth et al. does not perform the coagulation necrosis transmurally, i.e., through the entire width of the wall of the prostrate, as this would cause a rupture of the prostate as the entire wall thickness would slough off. Figs. 11B-11C show that the coagulation necrosis is only performed through a portion of the wall of the prostate.

Further, in the animal studies section, Roth et al. indicates that initial results were not satisfactory when the laser beam perforated the urethral tissue between the prostate and the bladder of the first two dogs treated. Although transmural ablation had previously been recited in claim 1, Applicants have further amended claim 1 to even more clearly differentiate over Roth et al. by reciting that a lesion formed by the transmural ablation forms an electric conduction block through an entire wall thickness of the tissue where the transmural ablation is performed. Claim 106 has been amended similarly. Support for these amendments can be found in the specification, for example at page 12, lines 25-29; page 15, lines 6-10; and page 25, lines 16-26, among others."

An Advisory Action was mailed on August 1, 2006 in which the Examiner refused to enter the Amendment filed on July 12, 2006. Applicants resubmitted the same Amendment with the Request for Continued Examination filed on September 5, 2006. In response thereto, the Examiner withdrew the rejection of claim 106 under 35 U.S.C. Section 102(b) as being anticipated by Roth et al., without comment, in the Office Action mailed September 28, 2006. In the Amendment filed January 29, 2007, claim 106 was amended to change "direct" to –emit--. In the Office Action responding thereto, which was mailed on March 7, 2007, the Examiner again did not reject claim 106 over Roth et al. In the Amendment filed May 2, 2007, Applicants again amended claim 106 to add further limitations thereto. No material was deleted from claim 106 in this amendment, so this amendment served to only further limit the claim. In the current Official Action mailed July 25, 2007, the Examiner has resurrected the rejection of claim 106 under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., without further comment. The prosecution history of claim 106 as rejected by Roth et al. does not appear to make logical sense. If claim 106 defined over Roth et al. with less limitations than it currently has, it is not understood how the Examiner can consider claim 106 to be suddenly clearly anticipated by Roth et al. after amending claim 106 to make it more limiting.

It is respectfully submitted that the amendment of claim 106 could not have necessitated the rejection over Roth et al., because claim 106 was amended to make it more limiting, and the Examiner had already previously decided that Roth et al. was overcome by a broader version of claim 106. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed concurrently herewith, the Examiner is respectfully requested to address the reasons why claim 106 should be considered to be anticipated by Roth et al., when the Examiner had previously withdrawn the rejection of claim 106 over Roth et al.

It is respectfully submitted that this ground of rejection is clearly inappropriate and should be withdrawn.

Claims Rejected Under 35 U.S.C. Section 102(e) (Sinofsky et al.)

Claims 106-107, 225, 240, 243, 246, 248-249, 253, 293-295 and 297 were rejected under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,365.

In the previous Amendment filed May 2, 2007 in response to the Office Action dated March 7, 2007, Applicants amended claim 106 to recite that said energy portion emits ablative energy substantially radially from a longitudinal axis thereof. Applicants noted that Sinofsky et al. discloses a light transmitting optical fiber 18 and a light diffusing element 32 including a scattering medium 28 make up the element 12, and that the light transmitting optical fiber emits light axially from the distal end of the optical fiber, not radially. Thus, when light is emitted axially from the distal end of the optical fiber 18, light is dispersed by the scattering particles 22, reflected by the reflective end 24 and scattered again.

In the Office Action of July 25, 2007, the Examiner did not address these asserted distinctions.

M.P.E.P. 707.07(f) requires that:

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>
> Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.
>
> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

In this case, it is respectfully submitted that the Examiner has ignored the amendment of claim 106 and the assertions made with regard thereto, as noted above. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed concurrently herewith, the Examiner is respectfully requested to address the amendment and remarks made by Applicants in the previous amendment which Applicants have referred to above.

It is respectfully submitted that this ground of rejection is clearly inappropriate and should be withdrawn.

Claim 107 has been amended above to further recite preventing rotation of said energy delivery portion relative to said guide catheter. Support for this amendment can be found in claim 225 and throughout the specification.

The Examiner referred to Fig. 2 of Sinofsky et al. as disclosing a non-circular cross-section. On page 4 of the Office Action dated July 25, 2007, the Examiner asserted that Fig. 4 of Sinofsky et al. clearly shows an oval cross section of the ablation sheath, with the complementary cross-section of the passage and the fiber being shown in Fig. 2. The Examiner asserted that it is well-understood that a claimed invention may be anticipated or rendered obvious by a drawing in reference, whether the drawing disclosure be accidental or intentional. Applicants respectfully traverse the Examiner's line of reasoning, since it is equally well-known that drawings are not considered to be drawn to scale, and therefore it is respectfully submitted that Sinofsky et al. does not provide the "teaching" that the Examiner is reading into the reference by the Examiner's interpretation of the drawings.

The Examiner himself has admitted that any light emitter, regardless of shape, will emit light in a circular pattern along its length. If this is true, then it appears clear that there would be no reason for Sinofsky et al. to prevent rotation of the optical fiber 18 relative to the ablation element 12, since the same pattern of light would be produced, relative to the ablation element 12, regardless of the rotational orientation of the optical fiber 18 thereto. It is for this reason that Sinofsky et al. does not provide a teaching preventing rotation of an ablation element relative to an ablation sheath.

The Examiner has interpreted the Figures of Sinofsky et al. to show a passage and a fiber that are each oval in cross-section. From this the Examiner made the conclusion that the fiber would not be able to rotate relative to the passage. Applicants respectfully traverse. The maximum outside diameter of the fiber 18 shown at the distal end of the device in Fig. 2 is about 7.5 mm. The minimum inside diameter of the passage formed by element 12 is about 9 mm. Accordingly, the inside wall of the element 12 would not prevent rotation of the fiber 18 regardless of whether the cross-sectional shapes are oval or not. Further, even if the minimum inside diameter of the passage formed by element 12 were the same or slightly smaller than the maximum outside diameter dimension of fiber 12, this would still not prevent rotation of fiber 18 relative to element 12, as there is clearly a large tolerance shown between the two elements in Fig. 2.

Accordingly, it is respectfully submitted that claim 107 defines over Sinofsky et al. for at least the reasons discussed above.

The Examiner further asserted that he interpreted Applicants to argue that the housing of Sinofsky et al. is the ablation device by itself. It is respectfully submitted that Applicants did not make

such an argument. Rather, Applicants identified element 12 as an ablation element, which is what Sinofsky et al. refers to it as, see column 3, line 17. With regard to claim 225, it is respectfully submitted that Sinofsky et al. does not disclose an ablation sheath having at least one lumen having a radially asymmetric geometry. Even if the Examiner interprets the passage of element 12 to be oval, the oval is still centered on the central longitudinal axis of the element 12 and is therefore radially symmetric about each of two transverse axes each perpendicular to the central longitudinal axis and perpendicular to each other, one transverse axis passing through the points identifying the largest diameter of the oval and the other transverse axis passing through the points identifying the smallest diameter of the oval. In contrast, the lumen shown in Figs. 8 and 9 is offset relative to the center 78 of the sheath and is radially asymmetric. New claim 301 has been submitted above to depend from claim 225 and to further recite that the lumen is offset from the center of the sheath.

Further, claim 225 recites that said radially asymmetric geometry of said at least one lumen prevents rotation of said ablative device with respect to the ablation sheath during the step of advancing. For reasons described above, it is respectfully submitted that Sinofsky et al. clearly fails to disclose this feature.

Regarding claims 246 and 248-249, Sinofsky et al. does not appear to disclose overlapping portions of a plurality of lesions to form a continuous lesion.

With regard to claims 293 and 297, Applicant again traverses the Examiner's assertion that Sinofsky et al. teaches prevention of rotation of the fiber 18 in the passage of element 12 in Fig. 2. Sinofsky is completely silent as to this so-called "teaching" in the written description of the patent, and Fig. 2 illustrates a tolerance between the elements 12 and 18 which would clearly allow at least a partial rotation of element 18 relative to element 12. Still further, since light from element 18 extends out perpendicular to the longitudinal axis of element 18 in all direction (360 degrees), this teaches against Sinofsky et al. having any need to prevent rotation of element 18 relative to element 12, since relative rotation of the components would not effect the performance thereof.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 106-107, 225, 240, 243, 246, 248-249, 253, 293-295 and 297 under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,365, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103 (Bednarek in combination with Sinofsky et al.)

Claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-104, 296, 298 and 299 were rejected under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375. The Examiner asserted that Bednarek teaches a method as claimed except for maintaining rotational alignment.

For reasons stated above with regard to the anticipatory-type rejections over Sinofsky et al., it is respectfully submitted that Sinofsky et al. also fails to teach or suggest maintaining rotational alignment.

The Examiner further asserted that Sinofsky et al. discloses a rotationally asymmetric cross-section. Without agreeing or disagreeing with the Examiner's assertion, Applicants note that none of the rejected claims recite "a rotationally asymmetric cross-section". It is further submitted that Sinofsky et al. does not disclose a radially asymmetric geometry as claimed, for reasons already expressed above.

As argued previously, Applicants respectfully submit that neither Sinofsky et al., nor Bednarek discloses or suggests maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen during transluminally slidably positioning steps. Sinofsky et al. discloses that light transmitted into the housing 26 is scattered in a circular pattern along the length of the ablation element. Accordingly, Sinofsky et al. teaches against maintaining rotational alignment, since rotational alignment is not necessary. Rotational alignment is not necessary with the device of Sinofsky et al. because light is scattered in a circular pattern. Accordingly, the rotational orientation of the light fiber 18 relative to the housing 26 is inconsequential.

Accordingly, it is respectfully submitted that independent claim 1, and claims depending therefrom are allowable over the combination of Sinofsky et al. and Bednarek for at least the reasons given above.

With regard to claim 51, it is respectfully submitted that neither Bednarek nor Sinofsky et al. provides or teaches a key assembly to properly align the energy delivery portion within the distal end of the flexible tubular member as claimed. As noted above, it is respectfully submitted that Sinofsky et al. does not teach maintenance of rotational alignment, contrary to the Examiner's indications. It is further respectfully submitted that Sinofsky et al. neither discloses nor suggests a key assembly. Nor does Bednarek teach or disclose maintenance of rotational alignment or the provision of a key assembly. Accordingly, Applicants respectfully submit that no teaching or suggestion is provided by either reference that would have led one of ordinary skill in the art to provide a key assembly with either the Bednarek device or the Sinofsky et al. device, contrary to the Examiner's assertions.

With regard to claim 52, it is respectfully submitted that neither Bednarek nor Sinofsky et al. teaches or suggests the provision of a microwave antenna assembly being adapted to direct the majority of the electromagnetic field generally in a predetermined direction across a distal end portion of a flexible tubular member. The only directionality provided by Bednarek that is apparent is by the openings in the introducer, not provided by a microwave antenna. The device of Sinofsky et al. is not a microwave antenna, and directs laser energy in all directions.

Likewise, with regard to claim 53, it is respectfully submitted that neither Bednarek nor Sinofsky et al. discloses or suggests providing a microwave ablation element comprising a microwave antenna configured to generate said electromagnetic field substantially radially form a longitudinal axis of the antenna.

With regard to claim 54, it is respectfully submitted that neither Bednarek nor Sinofsky et al. provides or suggests a key assembly as claimed or a microwave antenna as claimed, for reasons already provided above.

With regard to claim 59, it is respectfully submitted that neither Bednarek nor Sinofsky et al. provides or suggests a key assembly as claimed to properly align a laser emitting assembly within the distal end portion of the flexible tubular member. As noted above, alignment of the fiber of Sinofsky et al. is not required, since laser light is reflected radially in all directions. Further, Bednarek fails to disclose or suggest alignment with a key assembly.

With regard to claim 64, it is respectfully submitted that neither Bednarek nor Sinofsky et al. provides or suggests a key assembly as claimed to properly align an ultrasound ablation assembly within the distal end of the flexible tubular member as claimed.

With regard to claim 100, it is respectfully submitted that neither Bednarek nor Sinofsky et al. discloses or teaches a tubular member having a window portion formed of an electrically conductive material. Sinofsky et al. provides a tube that allows laser light to pass therethrough. Bednarek provides openings in the introducer.

With regard to claim 101, it is respectfully submitted that neither Bednarek nor Sinofsky et al. discloses or teaches a tubular member that includes a window portion formed of a dielectric material having a low loss coefficient at microwave frequencies. Sinofsky et al. provides a tube that allows laser light to pass therethrough. Bednarek provides openings in the introducer.

With regard to claim 104, it is respectfully submitted that neither Bednarek nor Sinofsky et al. discloses or teaches a tubular member that includes a window portion formed of a of a thermal conductor and said ablative device comprises a cryoablation element. Sinofsky et al. provides a tube

that allows laser light to pass therethrough. Bednarek provides openings in the introducer.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-104, 296, 298 and 299 under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al. and Cox et al.)

Claims 6-8, 12-13, 17-22, 40-42, 70, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187 and "the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures".

Applicants again emphasize here that there is a distinct difference between taking "Official Notice" that key assemblies are known, and the assertion that it would have been obvious to apply a key assembly in one of the assemblies of Bednarek or Sinofsky et al. It is respectfully submitted that a key assembly is not required to indicate the orientation of a surgical device to a surgeon, as the surgeon can simply look at the orientation of the device as it is held in his hand. Neither Bednarek nor Sinofsky et al. disclose or suggest the importance of maintaining a predetermined rotational orientation of an ablation element relative to a tube that it is inserted into. As noted above, the orientation of the fiber of Sinofsky et al. relative to the outer tube clearly does not matter. Nor does the orientation appear to be of a concern in the assembly of Bednarek. Accordingly, the Examiner has applied improper hindsight to develop a motivation for providing Bednarek or Sinofsky et al. with a key assembly, as the only

motivation provided for the same is that provided by the disclosure of the instant application.

The same reasoning can be applied to assessing the electrical isolation of the vein, by pacing the distal electrode to "capture" the heart, as this is neither taught nor disclosed by any of the cited references.

With regard to claims 6-8, it is respectfully submitted that these claims are allowable for the same reasons provided above with regard to claims 1 and 5, as they depend therefrom and since Cox et al. does nothing to make up for the deficiencies of Bednarek and Sinofsky et al. in meeting the recitations of claims 1 and 5.

With regard to claim 12, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of positioning the distal end portion of the flexible tubular member adjacent to or in contact with at least a portion of the transverse sinus preparatory to treating atrial fibrillation. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 13, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of positioning the distal end portion adjacent to or in contact with at least a portion of the oblique sinus preparatory to treating atrial fibrillation. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 70, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of a flexible tubular member comprising one or more electrodes coupled to a distal end portion thereof, and sensing contact between the flexible tubular member and the tissue region to be ablated using the one or more electrodes. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 79, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of measuring a temperature <u>from within</u> the flexible tubular member at one or more locations within the tubular member using the temperature sensor. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature.

Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 225, it is respectfully submitted that this claims is allowable over the combination of references applied thereagainst, since none of the references teaches or discloses a lumen having a radially asymmetric geometry, or preventing rotation of said ablative device with respect to the ablation sheath during the step of advancing to orient the predetermined direction toward said tissue surface. The reasons why Bednarek and Sinofsky et al. fail to disclose these features have been discussed in detail above. With regard to Cox et al., Applicants were unable to find a disclosure by Cox et al., of these features, and the Examiner has not identified a disclosure by Cox et al. of these features. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 232, Applicants have previously noted that it is at least arguable whether or not it would have been obvious to modify the sheath (the Examiner was not clear as to which reference the sheath to be modified is disclosed in) with a cutting member on the distal end thereof, as suggested by the Examiner. For this reason, Applicants respectfully submitted that the Examiner's statement of obviousness is not supported by simply asserting "official notice". Applicants respectfully submit that a question of obviousness cannot generally be supported as a statement of "fact". Accordingly, it is respectfully submitted that the application of "official notice" as a sole means of establishing a prima facie case of obviousness is generally improper, as application of official notice is to be limited to facts and statements of obviousness are not statements of facts.

It is noted that the Examiner did not address this traversal from the previous Amendment filed May 2, 2007.

M.P.E.P. 707.07(f) requires that:

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>
> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

In this case, the Examiner has ignored the traversal of the rejection of claim 232 based on "official notice", and has repeated the rejection thereof, based on the same grounds, without addressing Applicants' amendment or remarks. As such, it is respectfully submitted that the Office Action dated

July 25, 2007 is incomplete and not fully responsive to Applicants amendments and remarks. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed concurrently herewith, the Examiner is respectfully requested to address the amendment and remarks made by Applicants in the previous amendment which Applicants have referred to above.

It is respectfully submitted that this ground of rejection is clearly inappropriate and should be withdrawn.

With regard to claim 239, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of performing at least a portion of a coronary artery bypass graft procedure prior to or after said formation of at least one lesion. The Examiner is respectfully requested to supply a reference that teaches this feature, or swear out an affidavit as to the Examiner's personal knowledge that such procedures were carried out prior to the effective filing date of the instant application.

With regard to claim 241, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of positioning the distal end portion of the sheath adjacent to or in contact with at least a portion of the transverse sinus preparatory to treating atrial fibrillation. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 242, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of positioning the distal end portion of the sheath adjacent to or in contact with at least a portion of the oblique sinus preparatory to treating atrial fibrillation. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 245, Applicants were unable to find a disclosure by Cox et al., and the Examiner has not identified a disclosure by Cox et al. of puncturing at least one portion of the pericardial reflection located around a pulmonary vein. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 254, Applicants were unable to find a disclosure by Cox et al., and the

Examiner has not identified a disclosure by Cox et al. of an ablative device that includes a fluid delivery probe. It is further respectfully submitted that neither Bednarek nor Sinofsky et al. disclose this feature. Accordingly, if the Examiner intends to maintain this rejection, the Examiner is requested to specifically identify where, in at least one of the three cited references, that this feature is disclosed.

With regard to claim 282, the methods of Cox et al. and Bednarek appear to be endocardial procedures, and Sinofsky et al. appears to provide no teachings as to procedures. Accordingly, it is respectfully submitted that none of the applied references, taken in any proper combination, discloses teaches or suggests "manipulating the malleable distal end portion to create a desired shape of an ablation path"; or "positioning the distal end portion of the malleable tubular member in contact with a location on an epicardial surface of the heart near a pulmonary vein"; or "ablating tissue to form a lesion around the pulmonary vein with the at least one ablating element positioned proximate to the location on the epicardial surface to form at least part of the lesion around the pulmonary vein".

Further, in the Amendment filed May 2, 2007, Applicants traversed this ground of rejection of claim 282, respectfully submitting that Cox et al. does not teach the providing of a malleable tubular member through which at least one ablation element is transluminally slid.

It is noted that the Examiner did not address this traversal from the previous Amendment filed May 2, 2007.

M.P.E.P. 707.07(f) requires that:

> In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.
>
> Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.
>
> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

As such, it is respectfully submitted that the Office Action dated July 25, 2007 is incomplete and not fully responsive to Applicants amendments and remarks. Accordingly, it is respectfully submitted that the Office Action dated July 25, 2007 was improperly made Final. In view of the filing of the Request for Continued Examination filed concurrently herewith, the Examiner is respectfully requested to address the amendment and remarks made by Applicants in the previous amendment which Applicants have referred to above.

It is respectfully submitted that this ground of rejection is clearly inappropriate and should be withdrawn.

With regard to claim 290, it is respectfully submitted that none of the applied references teaches positioning a distal end portion of a malleable tubular member in contact with at least a portion of the transverse sinus location on the epicardial surface.

With regard to claim 291, it is respectfully submitted that none of the applied references teaches positioning a distal end portion of a malleable tubular member in contact with at least a portion of the oblique sinus location on the epicardial surface.

With regard to claim 292, it is respectfully submitted that none of the applied references teaches emitting unidirectional ablation energy and directing it toward the epicardial surface.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 6-8, 12-13, 17-22, 40-42, 70, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187 and "the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures", as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Swanson et al.)

Claims 70-79 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012. The Examiner asserted that Swanson et al. teaches using temperature sensors to control ablation and electrodes to pace, map, etc., the heart in a

maze procedure wherein the pulmonary vein is encircled. The Examiner asserted that it would have been obvious to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek, Sinofsky et al. and Cox et al. since this would enable the performance of beneficial cardiac procedures, such as maze or to employ the longitudinally translatable ablation element of the combined method of Bednarek, Sinofsky et al. and Cox et al. in the method of Swanson et al. since this can create longer lesions with a single ablation element.

Applicants respectfully traverse. Claims 70-79 depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen. Swanson contributes nothing to overcome this defect.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 70-79 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Kesten et al.)

Claims 80-91 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469. The Examiner asserted that Kesten et al. teaches delivering ablation devices with a pre-shaped sleeve to reach the ventricles via the peripheral veins, and that it would have been obvious to employ the sheath, delivering route and treatment region of Kesten et al. in the combined method of Bednarek et al., Sinofsky et al. and Cox et al., or to employ the directional slidable probe in a sheath of the combined method of Bednarek, Sinofsky et al, Cox et al. and Kesten et al., since this would allow the treatment of an elongated area without repositioning the device, and in either case,

to treat one of the atria or ventricles.

Applicants respectfully traverse. Applicants respectfully submit that claims 80-91 depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen, as Kesten et al. does not deliver ablative energy through an ablation sheath or tubular member, but extends the therapeutic device 3 distally out of the open end of the delivery catheter to apply therapy.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 80-91 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469, as being inappropriate.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-117.

Respectfully submitted,

LAW OFFICE OF ALAN W. CANNON

Date: 10/22/07

By: _____

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Signature	Maria J. Sousa	**Date**	10/22/2007

SUBMISSION OF REPLACEMENT AND NEW DRAWINGS

Address to:
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P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.	GUID-117
Confirmation No.	7176
First Named Inventor	Mody
Application Number	09/751,472
Filing Date	12/29/2000
Group Art Unit	3735
Examiner Name	Shay, David M.
Title:	Tissue Ablation Apparatus with a Sliding Ablation Instrument and Method

Sir:

Enclosed is a Replacement Sheet for Figs. 10 and 11, a Replacement Sheet for Figs. 21 and 22, and a New Sheet for new Fig. 23. The Replacement Sheet for Figs. 10 and 11 is to shown temperature sensor 27t in Fig. 11 and the Replacement Sheet for Figs. 21 and 22 is to remove improper shading. Please enter the enclosed Replacement Sheets and New Sheet to replace the currently existing Figs. 10, 11, 21 and 22, and to add new Fig. 23 in the instant application.

Respectfully submitted,
LAW OFFICE OF ALAN W. CANNON

Date: 10/22/07

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